UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ANTHONY J. MCHUGH
AND JESSICA R. DESNOYER

Appeal No. 2007-0307
Application No. 09/733,640
Technology Center 1616

ON BRIEF

Before SCHEINER, ADAMS, and MILLS, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

The Appellants appeal the examiner's final rejection of claims 1, 3-8, 17-19, 34, 38, and 49-72. Claims 2, 9-12, 20-33, 35-37, and 39-48 have been cancelled.

We have jurisdiction under 35 U.S.C. § 6(b) (2002).

We affirm.

Claim 1 is directed to:

> 1. An injectable composition for controlled release of a bioactive agent, comprising:
> a biodegradable crystallizable polymer;
> a biodegradable amorphous polymer;
> a biocompatible solvent having a miscibility with water less than 7 percent by weight; and
> a bioactive agent.
>
> 34. A method of administering a bioactive agent, comprising:
> inserting an injectable composition for controlled release of a bioactive agent into an organism, wherein the composition comprises:
> a biodegradable crystallizable polymer;
> a biodegradable amorphous polymer;
> a biocompatible solvent having a miscibility with water less than 7 percent by weight; and
> a bioactive agent.
>
> 38. A method of making an injectable composition for administering a bioactive agent, comprising:
> combining ingredients, wherein said ingredients comprise
> a biodegradable crystallizable polymer;
> a biodegradable amorphous polymer;
> a biocompatible solvent having a miscibility with water less than 7 percent by weight; and
> a bioactive agent.

Grounds of Rejection

1. Claims 1, 5-7, 17-18, 34, 38, 51-53, 55-56, 58, 60, and 66-67 stand rejected under 35 U.S.C. § 102(b) over Lundgren.

2. Claims 1, 3, 5-7, 17-18, 34, 38, 49, 51-53, 55-56, and 58-72 stand rejected under 35 U.S.C. § 103(a) over Shukla in view of Lundgren.

3. Claims 1, 3-19, 34, 38, and 49-72 stand rejected under 35 U.S.C. § 103(a) over Brodbeck in view of Lundgren.

4. Claims 3-4, 8, 19, 49-50, 54, 57, 59, 61-65, and 68-72 stand rejected under 35 U.S.C. § 103(a) over Lundgren in view of Brodbeck.

5. Claims 1, 3, 5, 34, 38, 49-51, and 58-72 stand rejected under 35 U.S.C. § 103(a) over Shukla in view of Bateman.

Rejections 1-4 are affirmed. Rejection 5 is reversed.

References cited:

Bateman	WO 88/07366	Oct. 6, 1988
Lundgren	US 5,525,646	Jun. 11, 1996
Brodbeck	US 6,130,200	Oct. 10, 2000
Shukla	US 6,432,438B1	Aug. 13, 2002

DISCUSSION

Anticipation

1. Claims 1, 5-7, 17-18, 34, 38, 51-53, 55-56, 58, 60, and 66-67 stand rejected under 35 U.S.C. § 102(b) over Lundgren.

Appellants group independent claims 1 and 38, together for purposes of this rejection and do not provide separate argument for individual claims (Br. 7-8). We select claim 1 as representative of this rejection. 37 C.F.R. §41.37(c)(1)(vii). Appellants provide separate argument for claim 34 (Br. 10), and we address this claim separately in the Decision.

With respect to composition claim 1, the Examiner contends that Lundgren discloses a bioresorbable material that comprises at least one amorphous polymer or a copolymer selected from the group consisting of poly-d,l-lactide, and copolymers of poly-d,l-lactide and polycaprolactone, poly-l-lactide, or

polytrimethylene and at least one crystalline polymer selected from poly-l-lactide, polycaprolactone and polydioxanone and a plasticizer including the solvent acetyltributyl citrate (Answer 3).

Appellants contend that Lundgren "teaches away" from injectable compositions (Br. 7) and that there is no description that the compositions of Lundgren can be injected (Br. 8).

The Examiner, however, contends that the term "injectable" in the preamble of the claim is a recitation of intended use of the composition (Answer 12).

"If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes Inc. v. Hewlett Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). A claim preamble that is more than a mere statement of purpose and essential to particularly point out invention defined by claims is considered as part of claimed invention. *In re Bulloch*, 604 F.2d 1362, 1366, 203 USPQ 171, 174 (CCPA 1979).

In the present case, the term "injectable composition" in the preamble of the claim defines characteristics or properties of the composition. The composition must be of such a nature (viscosity, etc.) to make it "injectable." Thus, in our view, the term "injectable" in the claim is a feature of the claimed composition for the purpose of determining patentability.

The Examiner argues that Appellants have not presented argument that the claimed composition and the composition of Lundgren are different (Answer 12). The examiner further argues that both the composition of Lundgren and the claimed composition exist in polymer solution before solidifying into a three-dimensional depot. The Examiner concludes, for this reason, that the "composition

claimed by applicant is also an intermediate prior to solidification in the body" and that Lundgren's polymer solution is capable of performing the intended use, that is, capable of being injected. Thus Lundgren's composition is "capable of being injected" or "injectable" within the meaning of the claim (Answer 12-13).

We agree with the Examiner that Lundgren's composition, when in solution, is "capable of being injected", making the composition "injectable" within the meaning of the claim 1, and also within the meaning of claim 34. With respect to claim 34, the Examiner interprets the phrase "inserting an injectable composition" as inserting a composition which is "capable of being injected" (Answer 15). This claim language does not require "injection" of a composition, but merely "insertion" of a composition. Thus, we agree with the Examiner's interpretation of claim 34. We further note the Examiner has indicated that claim 59, reciting "inserting by injection an injectable composition," contains allowable subject matter (Answer 16). In sum, there is a clear distinction in claim meaning between the claim language "inserting an injectable composition" in claim 34 and "inserting by injection an injectable composition" in claim 59.

In addition, Appellants' Specification states

> For an implant administered by injection, the fluid mixture transforms into a depot upon contact with the native fluid in the body. This depot is characterized by its phase separation from the physiological fluid and its decreased fluidity relative to the original mixture. The depot may be a semifluid gel, it may be a solid, or it may have an intermediate rigidity. It is this depot that serves as the polymeric implant for controlled release of the bioactive agent.
>
> Since the implant systems of the present invention preferably are formed as viscous gels, the means of administration of the implants is not limited to injection, although that mode of delivery may often be preferred. Where the implant will be administered as a leave-behind product, it may be formed to fit into a body cavity existing after

> completion of surgery or it may be applied as a flowable gel by brushing or palleting the gel onto residual tissue or bone. . . . . It is also possible to form the depot outside the body and then to implant the depot surgically.

Specification, 16-17.

Thus, in view of the above teachings in the specification, the claimed "injectable" composition can be inserted or implanted into the body, much in the same manner as the biorresorbable material and articles described in Lundgren. Thus, we do not find that Lundgren "teaches away" from the claimed composition (claims 1 and 38) or method (claim 34). The rejection of the claims for anticipation over Lundgren is affirmed.

Obviousness

2. Claims 1, 3, 5-7, 17-18, 34, 38, 49, 51-53, 55-56, and 58-72 stand rejected under 35 U.S.C. § 103(b) over Shukla in view of Lundgren.

Appellants group independent claims 1, 34, and 38 together for purposes of this rejection and do not provide separate argument for individual claims. Brief, pages 13-16. We select claim 1 as representative of this rejection. 37 C.F.R. § 41.37(c)(1)(vii).

Shukla teaches a biodegradable vehicle containing a drug and at least two plasticizers (solvent) and a biodegradable polymer (Answer 19). The biodegradable polymer may be two different biodegradable polymers with varying crystallinity and amorphous states to tailor the release characteristics of the delivery system (Id.).

The Examiner acknowledges that while Shukla teaches the blending of polymers according to their properties to manipulate release rate, Shukla does not exemplify the use of a polymer blend consisting of amorphous polymer and crystalline polymer (Answer 5). Shukla exemplifies an amorphous polymer (Id.). Shukla discloses that its biodegradable composition is injected (Shukla, col. 9, l. 24).

The Examiner relies on Lundgren for its disclosure "that a small amount of crystalline polymers to amorphous polymers drastically reduces swelling of the material." (Answer 5).

Thus, with respect to claims 1 and 38, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to combine the teachings of Shukla and Lundgren and add a biodegradable polymer to a crystalline powder (Answer 6). As to motivation, the Examiner argues, "[o]ne would have been motivated to add a crystalline polymer to Shukla's implant composition to provide mechanical strength to the implant once it is inserted in the body and reduce swelling of the material in the body" (Id.).

The Appellants contend that Lundgren's compositions for use in tissue regeneration "teach away" from the injectable vehicles of Shukla, stating that Shukla's compositions lacking dimensional stability are unsatisfactory for tissue regeneration, citing Lundgren, col. 1, ll. 27-32 and 45-51 (Br. 12).

The Examiner argues, on the other hand, that Appellants' "teaching away" arguments are unsubstantiated, and that "[t]he stability of the implant after solidification does not mean it cannot be injectable." (Answer 21). The Examiner argues that the composition of Lundgren exists in a solution state prior to solidification, and therefore is "injectable" (Id.). In addition, with respect to claim 34, the composition of Shukla is injected (Shukla, col. 1, l. 24).

As indicated above in relation to the rejection over Lundgren, we do not agree with Appellants that Lundgren "teaches away" from an injectable composition. We have no evidence of record proffered by Appellants establishing that the solvent composition of Lundgren is not injectable. Therefore, the rejection of the claims for obviousness over Shukla in view of Lundgren is affirmed.

3. Claims 1, 3-19, 34, 38, and 49-72 stand rejected under 35 U.S.C. § 103(b) over Brodbeck in view of Lundgren.

Appellants group independent claims 1, 34, and 38 together for purposes of this rejection and do not provide separate argument for individual claims. Brief, page 13. We select claim 1 as representative of this rejection. 37 C.F.R. §41.37(c)(1)(vii).

Appellants acknowledge that Brodbeck discloses a combination of a biocompatible polymer and a biocompatible solvent for controlled delivery of a beneficial agent (Br. 12). The composition can be a viscous gel, and may be modified to be less viscous in order to administer the composition through a needle (Brodbeck, col. 9, ll. 8-13). The composition of Brodbeck is implantable (Id., Abstract).

Again, Appellants contend that Lundgren "teaches away" from the viscous gels of Brodbeck, stating that Lundgren indicates that Brobeck's compositions lacking dimensional stability are unsatisfactory for tissue regeneration as in Lundgren (Br. 12). Appellants also argue Lundgren "teaches away" from an injectable composition (Br. 13).

However, the disclosures of Brobeck and Lundgren are not limited to compositions for tissue regeneration. The Examiner finds that Lundgren teaches adding a small amount of crystalline polymer to amorphous polymer to drastically

reduce the swelling of the material, thus providing motivation to add a crystalline polymer to increase the mechanical strength of the implant (Answer 22). In our view, the Examiner has provided relevant motivation found in the prior art to combine the cited references.

As indicated above, in relation to the rejection over Lundgren, we do not agree with Appellants that Lundgren "teaches away" from an injectable composition (claims 1 and 38). Moreover, with respect to instant claim 38, Brobeck teaches an injectable composition (Brodbeck, col. 9, ll. 8-13). With respect to each of claims 1, 34, and 38, we have no evidence of record establishing that the solvent containing composition of Lundgren is not "capable of being injected" or "injectable".

In view of the above, the rejection of the claims for obviousness over Brodbeck in view of Lundgren is affirmed.

4. Claims 3-4, 8, 19, 49-50, 54, 57, 59, 61-65, and 68-72 stand rejected under 35 U.S.C. § 103(b) over Lundgren in view of Brodbeck.

The same analysis and conclusion can be drawn from the reverse combination of the cited references. The rejection is affirmed.

5. Claims 1, 3, 5, 34, 38, 51, and 58-72 stand rejected under 35 U.S.C. §103(b) over Shukla in view of Bateman.

Shukla is discussed above. The examiner acknowledges that Shukla does not exemplify the use of a polymer blend specifically comprising an amorphous polymer and a crystalline polymer (Answer 9). The Examiner further relies on Bateman which teaches that partially crystalline polymers provide for an immediate release of active agent whereas amorphous polymers provide for

prolonged release of an active agent (Answer 10). Bateman further teaches blending crystalline and amorphous polymers in various ratios can provide a range of active release rates for compressed tablets containing herbicides, industrial chemicals, veterinary agents and pharmaceutical (Id., see also, Bateman 4-5).

Appellants contend that there is no motivation to combine Shukla with Bateman, because the disclosure of Bateman is limited to solid tablet formulations (Br. 15). Appellants argue that there is no reasonable expectation of success that the composition of Bateman for release of an active agent in the digestive tract would work as a controlled release agent if implanted into a fixed position in the body (Br. 15-16).

We agree with Appellants that there is "no disclosure in . . . Bateman that would provide one of ordinary skill in the art with a reasonable expectation of success in the combination of a viscous vehicle for body cavities with a tablet for oral administration." (Br. 16).

Appellants argue that "the solid tablet of Bateman may be used for controlled release in an organism only by introduction into the digestive track, where it will come into contact with acids, enzymes and bacteria." (Id.).

Due to the differences in between Bateman's solid tablets administered to the digestive track, or including herbicides or chemicals, and the implantable compositions of Shukla exposed to an entirely different milieu, we do not find that the Examiner has provided sufficient motivation to combine Shukla and Bateman to establish a prima facie case of obviousness. This rejection is reversed.

CONCLUSION

The rejection of claims 1, 5-7, 17-18, 34, 38, 51-53, 55-56, 58, 60, and 66-67 under 35 U.S.C. § 102(b) over Lundgren is affirmed. The rejection of claims 1, 3,

5-7, 17-18, 34, 38, 49, 51-53, 55-56, and 58-72 under 35 U.S.C. § 103(b) over Shukla in view of Lundgren is affirmed. The rejection of claims 1, 3-19, 34, 38, and 49-72 under 35 U.S.C. § 103(b) over Brodbeck in view of Lundgren is affirmed. The rejection of claims 3-4, 8, 19, 49-50, 54, 57, 59, 61-65, and 68-72 under 35 U.S.C. § 103(b) over Lundgren in view of Brodbeck is affirmed. The rejection of claims 1, 3, 5, 34, 38, 51, and 58-72 under 35 U.S.C. § 103(b) over Shukla in view of Bateman is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

TONI R. SCHEINER)
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)
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Administrative Patent Judge)
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